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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT

PAPER NUMBER

1637

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/743,975	Applicant(s) DAVYDOVA ET AL.	
	Examiner Angela M. Bertagna	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Applicant's response filed on July 22, 2009 is acknowledged. Claim 93 is currently pending. In the response, Applicant canceled claims 83-92 and 94.

Applicant's cancellation of claims 83-92 and 94 and submission of a terminal disclaimer have overcome all of the previously made rejections, and therefore, they have been withdrawn.

The following are new grounds of rejection. Since the new grounds of rejection were not necessitated by Applicant's amendment, this Office Action is made **NON-FINAL**.

Drawings

2. The drawings are objected to, because Figures 1 and 2 recite a nucleic acid sequence that is greater than ten nucleotides in length and a polypeptide sequence that is greater than four amino acids in length, respectively, that have not been identified by the appropriate SEQ ID NO either in the drawing or in the "Brief Description of the Drawings" section. See 37 CFR 1.821(b) and MPEP 2422.02

If Applicant elects to insert the required sequence identifiers into Figures 1 and 2, Applicant is reminded that any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities:

(A) The continuity information appearing in the first paragraph of the specification should be updated to indicate that Application Serial No. 10/153,219 has issued as US Patent No. 7,452,705.

(B) The specification contains polypeptide sequences greater than four amino acids in length that have not been identified by the appropriate SEQ ID NO as required by 37 CFR 1.821-1.825. The polypeptide sequences requiring identification appear on page 19 (paragraph 43), page 28 (paragraph 78), page 69 (paragraph 231), and page 177 (paragraph 574).

(C) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 57). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

(D) The disclosure is also objected to, because the drawings show Figures 22A and 22B, but the "Brief Description of the Drawings" section only refers to Figure 22. As noted in MPEP 608.01(f), "If the drawings show Figures 1A, 1B, and 1C and the brief description of the

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drawings refers only to Figure 1, the examiner should object to the brief description, and require applicant to provide a brief description of Figures 1A, 1B, and 1C."

(E) The use of trademarks (*e.g.* TALON, LABCHIP, TEXAS RED, R&DNA POLYMERASE, and MASTERPURE – see pages 20, 72, 77, 85, and 90, for example) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claim 93 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 7,452,705. Although the conflicting claims are not identical, they are not patentably distinct from each other, because it would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to practice the method of claim 93 using the compositions recited in claims 1-16 of the '705 patent. Also, the method recited in claims 17-27 of the '705 patent suggests the method of the instant claim 93.

The instant claim 93 is drawn to a method for making RNA that comprises combining a single-stranded DNA oligonucleotide having an N4 virion RNA polymerase promoter sequence with an N4 virion RNA polymerase, specifically mini-vRNAP or the Y678F mutant form of mini-vRNAP, and incubating the resulting mixture under conditions effective to allow RNA synthesis.

Claims 1-5 and 13-16 of the '705 patent are drawn to isolated nucleic acids that encode mini-vRNAP or the Y678F mutant form of the N4 virion RNA polymerase. Claims 6-11 of the '705 patent are drawn to isolated recombinant host cells containing one of the nucleic acids of claim 1. Claim 12 of the '705 patent is drawn to a recombinant vector that comprises a DNA segment that encodes N4 mini-vRNAP or the Y678F mutant form of N4 mini-vRNAP. Claims 17-27 of the '705 patent are drawn to a method of making a full-length N4 vRNAP or N4 mini-vRNAP.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to use the N4 mini-vRNAP or Y678F mutant form N4 mini-vRNAP recited in the claims of the '705 patent to practice the method of making RNA recited in the instant claim 93. Since claims 1-27 of the '705 patent teach that the recited nucleic acid products encode an N4

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mini-vRNAP or a Y678F mutant form of mini-vRNAP, an ordinary artisan would have been motivated to use the RNA polymerase encoded by the products of claims 1-5 and 13-16, produced by the products of claims 6-12, or produced by the methods of claims 17-27 for its intended purpose (RNA synthesis) with a reasonable expectation of success. As noted in MPEP 2144.07, it is *prima facie* obvious to utilize a known material for its intended purpose in the absence of unexpected results. In this case, the ordinary artisan would have recognized from the teachings of the claims of the '705 patent that the recited N4 mini-vRNAP or Y678F mini-vRNAP was suitable for use in a method of making RNA that comprises combining a single-stranded DNA oligonucleotide having an N4 virion RNA polymerase promoter sequence with either N4 mini-vRNAP or the Y678F mutant form of N4 mini-vRNAP and incubating the resulting mixture under conditions effective to allow RNA synthesis. It is also noted that no evidence of unexpected results has been presented. Further, it is noted that the instant application is a continuation-in-part of the application that issued as the '705 patent, and therefore, the protections of 35 U.S.C. 121 do not apply. Thus, the method of the instant claim 93 is *prima facie* obvious in view of claims 1-27 of the '705 patent.

6. Claim 93 is directed to an invention not patentably distinct from claims 1-27 of commonly assigned US Patent No. 7,452,705. Specifically, as discussed above, the method of the instant claim 93 is suggested by claims 1-27 of the '705 patent.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent No. 7,452,705, discussed above, would form the basis for a

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rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

7. Claim 93 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 172-197 of copending Application No. 10/719,372. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 172-197 of the '372 application recite a more specific embodiment of the method recited in the instant claim 93.

The instant claim 93 is drawn to a method for making RNA that comprises combining a single-stranded DNA oligonucleotide having an N4 virion RNA polymerase promoter sequence with an N4 virion RNA polymerase, specifically mini-vRNAP or the Y678F mutant form of mini-vRNAP, and incubating the resulting mixture under conditions effective to allow RNA synthesis.

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Independent claim 172 of the '372 application recites a method for making RNA that comprises combining a single-stranded DNA oligonucleotide having an N4 virion RNA polymerase promoter sequence with either the N4 mini-vRNAP or the Y678F mutant form of the N4 mini-vRNAP and incubating the resulting mixture under conditions that permit RNA synthesis. Therefore, claim 172 of the '372 application anticipates the method recited in the instant claim 93. Since claims 173-197 of the '372 application depend from claim 172 of the '372 application, these claims also recite all of the limitations of the instant claim 93. Accordingly, claims 172-197 of the '372 application anticipate the method recited in the instant claim 93.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Terminal Disclaimer

8. The terminal disclaimer filed on July 22, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Serial No. 10/719,913 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

9. Applicant's arguments filed on July 22, 2009 do not appear to address the previously made objection to the specification requiring updating of the continuity information presented in the first paragraph. Accordingly, this objection has been reiterated and maintained.

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As noted above, all of the previously made rejections have been withdrawn in view of the cancellation of claims 83-92 and 94 and the submission of a terminal disclaimer. Accordingly, Applicant's arguments filed on July 22, 2009 regarding these rejections have been considered, but they are moot, since they are directed to withdrawn rejections.

Conclusion

10. No claims are currently allowable. It is noted that claim 93 is free of the art, but it has rejected for other reasons, specifically on the ground of obviousness-type double patenting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela M. Bertagna whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela M. Bertagna/
Examiner, Art Unit 1637